

### **REMARKS**

Claims 25-31, 34-35, 37-40, 42, 46, 50, 52-59, 61, 62, 64-67, 69-70, 73, 75, 79, 81-85, 91-93, 94, 95-97, 101, 103, 105, 108, 109, 110, 111, and 112 are pending, with claim 94 being the only withdrawn claim. By this amendment, claims 25, 26, 27, 52, 53, 54, and 83 have been amended. The amendments to the claims are supported, for example, at page 22 lines 19-21, page 29 lines 10-11, page 32 lines 14-15, page 33, lines 24-26, and page 36 lines 3-31. No new matter has been introduced.

The election of species remains: (1) durum wheat as the plasticized matrix material, (2) a probiotic nutraceutical component as an encapsulant, (3) starch as the additional matrix material, and (4) liquid encapsulant as the encapsulant form. The claims readable on the elected species are Claims 25-31, 34-35, 37-40, 42, 46, 50, 52-59, 61, 62, 64-67, 69-70, 73, 75, 79, 81-85, 91-93, 95-97, 101, 103, 105, 108, 109, and 110, and new claims 111-112.

### **The Initialed Form PTO-1449**

The Examiner is thanked for initialing each of the references cited in the March 28, 2012 Supplemental Information Disclosure Statement.

### **The Obviousness Type Double Patenting Rejection**

The Examiner has noted that the Obvious Double Patenting Rejection made on March 17, 2003 was erroneously withdrawn before the Terminal Disclaimer filed on June 18, 2003 was approved. The Terminal Disclaimer was disapproved on April 12, 2012 and therefore the Obvious Double Patenting Rejection has been reinstated.

### **THE REJECTIONS UNDER 35 U.S.C. 103(a)**

Claims 25, 26, 28, 30, 31, 35, 37 40, 46, 91, 92, 101, 108 and 109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schiltz (US 5,449,708) in view of Farquharson

et al (US 4,888,174). This rejection is respectfully traversed for reasons as presented in the March 28, 2012 response and below.

Neither Schiltz nor Farquharson et al, taken alone or in combination teach or suggest the use of a plasticized mass comprising starch which is neither substantially destructured nor substantially dextrinized, as claimed in independent claims 25, 27, 52, 54, and 83, and their dependent claims. Even if the references were properly combinable, applicant's claimed products would not be obtained or rendered obvious.

The Examiner submits that the instant claims recite using pre-gelatinized starch in the compositions and therefore one of ordinary skill in the art would conclude that what Applicant considers "destructured" and "dextrinized" would not include gelatinized starches. However, a destructured starch and a dextrinized starch is gelatinized, because destructuring and dextrinization occur after gelatinization. A gelatinized starch or a pregelatinized starch does not have to be destructured and does not have to be dextrinized. As disclosed in the present application when a gelatinized starch or a pregelatinized starch is employed in the present invention, it is not substantially destructured and it is not substantially dextrinized. For example, see page 22 lines 19-23 which states:

In embodiments where starch is used as a matrix material, the starch is at least partially gelatinized without substantially destructure and dextrinizing the starch. The degree of gelatinization may, for example, be at least about 75%, for example, at least about 90%, or essentially completely gelatinized.

See also page 29 lines 10-11 which states:

The starch component of the matrices is at least partially gelatinized and not substantially destructure or dextrinized.

Also, regarding pregelatinized starch, the specification states at page 33 lines 24-26:

In this case, the moisture needs to be sufficiently high so as to provide sufficiently low viscosity without destructuring or dextrinizing the pregelatinized starch.

Gelatinization may be defined as the collapse (disruption) of molecular orders within the starch granule, manifested in irreversible changes in properties such as granular swelling, native crystallite melting, loss of birefringence, and starch solubilization. See Atwell et al., "The Terminology And Methodology Associated With Basic Starch Phenomena," Cereal Foods World, Vol. 33, No. 3, pgs. 306-311 (March 1988). However, destructuring of starch occurs after gelatinization and involves increased granular swelling, exudation of molecular components (i.e. amylose, followed by amylopectin) from the granule, and eventually, total disruption of the granules. Dextrinization involves breaking down of the molecular components into shorter chain molecules.

The Examiner maintains that the claims recite "not substantially destructured or dextrinized", which indicates that the starch may be one or the other (either "not substantially destructured" or "not substantially dextrinized") or both. According to the Examiner, therefore even if the starch is substantially destructured as applicant argues, the granules are "not substantially dextrinized", meeting the limitation of "not substantially destructured or dextrinized". The claims have been amended to more clearly indicate that the starch is neither substantially destructured nor substantially dextrinized. The starch of Schiltz is clearly substantially destructured, with the starch molecules being exuded from the granules for polymerization. The Examiner asserts that the instant specification discloses that the plasticized composition forms a melt, which indicates that the starch granules of the instant claims undergo some type of disruption. However, crystallinity of the molecules in the starch granules can be changed to amorphous regions within the starch granules, without having the molecules of starch exude from the granule. To the contrary, in the process of Schiltz, the starch molecules are exuded from the granules and the granules are destroyed, which is a substantial destructuring.

Schiltz discloses a method for the continuous preparation of a starch-based biodegradable polymer. A homogeneous mixture of starch, an ethylene acrylic acid co-polymer, and a salt of stearic acid are premixed before addition of an aqueous lubricant material. An increase in temperature gelatinizes the starch and melts the co-polymer. Excess moisture is removed under reduced pressure and a plastic material is extruded. The starch is gelatinized prior to and during dispersion within the ethylene acrylic acid copolymer and, optionally, polyethylene. According to Schiltz, “Gelatinization disrupts the starch granules, providing access to individual starch molecules. Extensive gelatinization is critical for compatibility of the starch with the copolymer component and, later, with respect to biodegradability.” An aqueous solution of lubricant, having a preferred pH, with the appropriate temperature and sheer forces, is employed to effect the desired degree of gelatinization. The Schiltz gelatinization “disrupts the starch granules and provides access to individual starch molecules to compatablize the starch for use in the plastic material, and at the same time increase biodegradation. See the abstract, paragraphs bridging columns 3 and 4, col. 4 lines 4 to 45, col. 5 lines 1-10 col. 6 lines 37-46 col. 8 lines 14-36. Schiltz clearly wants to destroy the starch granules so that the individual starch molecules or amylose can interact with the copolymer and polyethylene to form a polymer composite.

Schiltz does not teach or suggest avoiding destructuring or dextrinization, or the use of low shear or high amounts of plasticizer, or extrusion residence time, screw speeds, and screw configurations to achieve plasticization without substantial destructurization or dextrinization of the starch. To the contrary, Schiltz employs a critical pH of 10-12, preferably accomplished with the addition of sodium hydroxide, to disrupt the starch granules and provide access to individual starch molecules to achieve interaction between the components to obtain a polymer composite. See col. 8 lines 14-36.

The Examiner maintains that Farquharson et al discloses a composition comprising an insecticide and a polymer, the compositions may be formulated into films, and the compositions may be incorporated into polymer pellets, with the size of the pellet ranging in

diameter from about 1/16 to about 1/2 inch (1.58 mm to 12.7 mm). It is asserted that it would have been obvious to one of ordinary skill in the art to have made the pellets of Schiltz a size where the diameter ranges from 1/16 to 1/2 inch motivated by the desire to make pellets a size disclosed by the art as suitable for pellets used in agriculture.

Farquharson et al does not cure the above-discussed deficiencies in the disclosure of Schiltz. The reference does not disclose the use of starch or avoiding destructure or dextrinization of starch. Even if the pellet sizes employed by Farquharson et al were used in the process of Schiltz, applicant's claimed invention would not be obtained or rendered obvious.

Reconsideration and withdrawal of the rejection is respectfully requested.

Claims 25-31, 34, 35, 37-40, 46, 50, 52-59, 61, 62, 64-67, 69, 73, 75, 79, 81-83, 85, 91, 92, 93, 95-97, 101, 103, 105, 108, 109, 111, and 112 are rejected under 35 U.S.C. 103(a) as being unpatentable over Loomis et al (US 5,852,114) in view of Newton et al (US 4,938,967). This rejection is respectfully traversed for reasons as presented in the March 28, 2012 response and below.

Neither Loomis et al nor Newton et al, taken alone or in combination teach or suggest the use of a plasticized mass comprising starch which is neither substantially destructured nor substantially dextrinized, as claimed in independent claims 25, 27, 52, 54, and 83, and their dependent claims. Even if the references were properly combinable, applicant's claimed products would not be obtained or rendered obvious.

The Examiner maintains that in regard to the starches of Loomis et al being destructured, it is submitted that the instant claims recite using partially gelatinized starch in the compositions and therefore one of ordinary skill in the art would conclude that what Applicant considers "destructured" and "dextrinized" would not include gelatinized starches. However, as discussed above, a destructured starch and a dextrinized starch is gelatinized, because destructuring and dextrinization occur after gelatinization. A gelatinized starch or a

pregelatinized starch does not have to be destructured and does not have to be dextrinized. As disclosed in the present application when a gelatinized starch or a pregelatinized starch is employed in the present invention, it is not substantially destructured and it is not substantially dextrinized. For example, see page 22 lines 19-23 which states:

In embodiments where starch is used as a matrix material, the starch is at least partially gelatinized without substantially deconstructing and dextrinizing the starch. The degree of gelatinization may, for example, be at least about 75%, for example, at least about 90%, or essentially completely gelatinized.

See also page 29 lines 10-11 which states:

The starch component of the matrices is at least partially gelatinized and not substantially deconstructed or dextrinized.

Also, regarding pregelatinized starch, the specification states at page 33 lines 24-26:

In this case, the moisture needs to be sufficiently high so as to provide sufficiently low viscosity without deconstructing or dextrinizing the pregelatinized starch.

Gelatinization may be defined as the collapse (disruption) of molecular orders within the starch granule, manifested in irreversible changes in properties such as granular swelling, native crystallite melting, loss of birefringence, and starch solubilization. However, deconstructing of starch occurs after gelatinization and involves increased granular swelling, exudation of molecular components (i.e. amylose, followed by amylopectin) from the granule, and eventually, total disruption of the granules. Dextrinization involves breaking down of the molecular components into shorter chain molecules.

The Examiner maintains that the claims recite "not substantially destructured or dextrinized", which indicates that the starch may be one or the other (either "not substantially destructured" or "not substantially dextrinized") or both. According to the Examiner, therefore even if the starch is substantially destructured as applicant argues, the granules are "not substantially dextrinized", meeting the limitation of "not substantially

destructured or dextrinized". The claims have been amended to more clearly indicate that the starch is neither substantially destructured nor substantially dextrinized. The starch of Loomis et al is clearly substantially destructured, with the starch molecules being exuded from the granules for polymerization. The Examiner asserts that the instant specification discloses that the plasticized composition forms a melt, which indicates that the starch granules of the instant claims undergo some type of disruption, and Loomis et al disclose the compositions form melts. However, crystallinity of the molecules in the starch granules can be changed to amorphous regions within the starch granules, without having the molecules of starch exude from the granule. To the contrary, in the process of Loomis et al, the starch molecules are exuded from the granules and the granules are destroyed, which is a substantial destructuring. The Examiner asserts that applicant does not appear to provide any evidence that the conditions in Loomis et al would cause substantial destructurization or dextrinization.

Loomis discloses the use of extrusion temperatures of 170 to 205°C in the blending zone and within the range of 210 to 225°C in the last zone and the extruder die. See col. 14 lines 30-54. Loomis desires destructured starch and employs extrusion conditions to destructure starch. According to Loomis et al, "when starch is heated under shear in the presence of relatively small amounts of water, the resulting new starch-water composition, in the form of a melt, surprisingly has thermoplastic properties. Those thermoplastic starch compositions have become known as "destructured starch." See col. 2 lines 16-26. Loomis et al produces polymer blend compositions that are thermoplastic. See col. 1 lines 16-20. Loomis et al may include destructurized starch in the compositions to impart further desirable physical properties and characteristics. See col. 4 lines 59-67. If starch or gelatinized starch was employed, it would be subjected to the intense extrusion conditions which would destructure the starch. As disclosed by Loomis et al:

In compositions prepared from a first polymer, a second polymer and a polysaccharide component, such as a starch component, the starch component may be processed--e.g., gelatinized or destructurized--

independently from the first polymer and the second polymer, and then included in, or added to, the composition either before or after processing the components used to form the composition. Alternatively, the starch component may be included in the composition while processing the first polymer and the second polymer into the uniform, substantially homogeneous uniform blend. See col. 11 lines 16-25.

In accordance with the present invention, the compositions may be prepared by subjecting the components used to form the inventive compositions to conditions of intensive mixing, with elevated temperature, such as the conditions that are achieved within the screw and barrel of an extruder. The first polymer and the second polymer, and optionally a polysaccharide component, such as a starch component, may be introduced to intensive mixing conditions in the form of granules, pellets or powders, or in a plasticizer as slurries or solutions thereof. (Emphases added.) See col. 11 lines 38-49.

Processing under the intensive mixing conditions described herein should be continued at a temperature that is greater than the melting point of the first polymer, which itself is typically lower than the melting point of the second polymer, and for a time sufficient to cause the first polymer and the second polymer (and other optional components) to become intimately associated by way of blending to form a uniform, substantially homogeneous blend, and under appropriate conditions a melt-blend. (Emphasis Added). See col. 12 lines 22-30.

Also, as discussed above, Loomis employs extrusion temperatures of 170 to 205°C in the blending zone and within the range of 210 to 225°C in the last zone and die, and also a very high a L/D of 38, and the removal of any water in the first zone of the extruder, all of which would result in destructuring of starch. See col. 14 lines 18-54.

As discussed above, and as discussed in the present specification at, for example, the paragraph bridging pages 6 and 7, the paragraph bridging pages 7 and 8, the paragraph bridging pages 12 and 13, the paragraph bridging pages 22 and 23 to page 23 second full paragraph, and the first full paragraph on page 26, low shear mixing, low temperature and plasticizer amounts, and extrusion residence time, screw speeds, and screw configuration are



employed to achieve plasticization without substantial destructurization or dextrinization of the starch.

Loomis et al does not teach or suggest avoiding destructuring or dextrinization, or the use of low shear or high amounts of plasticizer, or extrusion residence time, screw speeds, and screw configurations to achieve plasticization without substantial destructurization or dextrinization of the starch. To the contrary, Loomis et al employs high extrusion temperatures, a high L/D, intensive mixing conditions, and low moisture contents to obtain destructured starch and a thermoplastic composition.

Furthermore, as evidence that the Loomis et al extrusion would result in destructuring of the starch component, as discussed in the March 28, 2012 Amendment, Bastioli et al discloses that from a microphotograph relating to their comparative experiment 1, it is apparent that the extrusion temperature of 100° C. is too low and does not allow the destructuring of the starch because the microphotograph shows the presence of a large number of still intact starch granules. The analysis, it is disclosed, of the product obtained from example 2 (extrusion temperature 120°C.) shows that the number of intact starch granules has been substantially reduced, although some are still present. On the other hand, it is disclosed, a complete destructuring of the starch is obtained according to example 3 with an extrusion temperature of 140°C. The microphotographs obtained from the material of example 3 does not show intact starch granules according to Bastioli et al. See Bastioli et al U.S. Patent No. 5,462,982 at col. 1 lines 24-36, col. 2 lines 20-41, and col. 4 lines 7-27. The Loomis et al method employs much more intense extrusion conditions than those of Bastioli et al which would clearly destroy intact starch granules resulting in substantial destructuring by the extrusion temperatures of 170 to 205°C in the blending zone and within the range of 210 to 225°C in the last zone and die, and also with the use of a very high L/D of 38, and the removal of any water in the first zone of the extruder, all of which would result in substantial destructuring of starch.

The Examiner maintains that Newton et al discloses applicant's density as conventional, the amount of active ingredient, pellet size, and coatings and it would be obvious to modify the Loomis et al compositions in accordance with the teachings of Newton et al. Newton et al does not cure the above-discussed deficiencies in the disclosure of Loomis et al. Even if the references were properly combinable, employment of a starch binder of Newton et al in the process and composition of Loomis et al would still result in substantial destructure of the starch because it would be subjected to the intense extrusion conditions of Loomis et al.

In regard to claims 111 and 112, the Examiner asserts that the starches used by Loomis et al include native and modified starches, which would meet the limitation of the starch being not cooked or a portion of it being not cooked. However, the native starch or modified starch of Loomis et al employed as an ingredient would still be substantially destructured because it would be subjected to the intense extrusion conditions of Loomis et al, as described above.

Reconsideration and withdrawal of the rejection is respectfully requested.

Claims 42, 69, 70, 84 and 108-110 are rejected under 35 U.S.C. 103(a) as being unpatentable over Loomis et al (US 5,852,114) in view of Newton et al (US 4,938,967) as applied to claims 25-31, 34, 35, 37-40, 46, 50, 52-59, 61, 62, 64-67, 69, 73, 75, 79, 81-83, 85, 91, 92, 93, 95-97, 101, 103, 105, 108 and 109 in further view of Tye et al (US 5,308,636). This rejection is respectfully traversed for reasons as presented in the March 28, 2012 response and below.

The comments above regarding Loomis et al and Newton et al are applicable here and incorporated herein. Tye et al does not cure the deficiencies in the disclosures of Loomis et al and Newton et al discussed above. Even if all three references were properly combinable, applicant's claimed invention would not be obtained or rendered obvious. None of the references, taken alone or in combination teach or suggest the use of a

plasticized mass comprising starch which is neither substantially destructured nor substantially dextrinized. Even if the references were properly combinable, employment of semolina of Tye et al in the process and composition of Loomis et al would still result in substantial destructurization of the starch because it would be subjected to the intense extrusion conditions of Loomis et al as discussed above.

Reconsideration and withdrawal of the rejection is respectfully requested.

Claims 25-31, 34, 35, 37-40, 46, 50, 52-59, 62, 64-67, 69, 73, 75, 79, 81-83, 85, 91, 92, 93, 95-97, 101, 103, 105, 108 and 109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newton et al (US 4,938,967) in view of Fishman et al (US 5,451,673). This rejection is respectfully traversed for reasons as presented in the March 28, 2012 response and below.

The Examiner admits that Newton et al does not teach a plasticized matrix. It is asserted that the secondary reference, Fishman et al, discloses a heated plasticized matrix and it would have been obvious to one skilled in the art to have used the heated plasticized matrix of Fishman et al in the formulations of Newton et al, motivated by the desire to use a composition that is suitable for carriers and encapsulation materials.

Neither Newton et al nor Fishman et al, taken alone or in combination teach or suggest the use of a plasticized mass comprising starch which is neither substantially destructured nor substantially dextrinized, as claimed in independent claims 25, 27, 52, 54, and 83, and their dependent claims. Even if the references were properly combinable, applicant's claimed products would not be obtained or rendered obvious.

The Examiner maintains that the instant claims recite using partially gelatinized starch in the compositions and therefore one of ordinary skill in the art would conclude that what Applicant considers "destructured" and "dextrinized" would not include gelatinized

starches. However, as discussed above, a destructured starch and a dextrinized starch is gelatinized, because destructuring and dextrinization occur after gelatinization. A gelatinized starch or a pregelatinized starch does not have to be destructured and does not have to be dextrinized. As disclosed in the present application when a gelatinized starch or a pregelatinized starch is employed in the present invention, it is not substantially destructured and it is not substantially dextrinized. For example, see page 22 lines 19-23 which states:

In embodiments where starch is used as a matrix material, the starch is at least partially gelatinized without substantially destructuring and dextrinizing the starch. The degree of gelatinization may, for example, be at least about 75%, for example, at least about 90%, or essentially completely gelatinized.

See also page 29 lines 10-11 which states:

The starch component of the matrices is at least partially gelatinized and not substantially destructured or dextrinized.

Also, regarding pregelatinized starch, the specification states at page 33 lines 24-26:

In this case, the moisture needs to be sufficiently high so as to provide sufficiently low viscosity without destructuring or dextrinizing the pregelatinized starch.

Gelatinization may be defined as the collapse (disruption) of molecular orders within the starch granule, manifested in irreversible changes in properties such as granular swelling, native crystallite melting, loss of birefringence, and starch solubilization. However, destructuring of starch occurs after gelatinization and involves increased granular swelling, exudation of molecular components (i.e. amylose, followed by amylopectin) from the granule, and eventually, total disruption of the granules. Dextrinization involves breaking down of the molecular components into shorter chain molecules.

The Examiner maintains that the claims recite "not substantially destructured or dextrinized", which indicates that the starch may be one or the other (either "not

substantially destructured" or "not substantially dextrinized") or both. According to the Examiner, therefore even if the starch is substantially destructured as applicant argues, the granules are "not substantially dextrinized", meeting the limitation of "not substantially destructured or dextrinized". The claims have been amended to more clearly indicate that the starch is neither substantially destructured nor substantially dextrinized. The starch of Fishman et al is clearly substantially destructured, with the starch molecules being exuded from the granules. The Examiner asserts that the instant specification discloses that the plasticized composition forms a melt, which indicates that the starch granules of the instant claims undergo some type of disruption, and Fishman et al disclose the compositions form melts. However, crystallinity of the molecules in the starch granules can be changed to amorphous regions within the starch granules, without having the molecules of starch exude from the granule. To the contrary, in the process of Fishman et al, the starch molecules are exuded from the granules and the granules are destroyed, which is a substantial destructuring. The Examiner asserts that applicant does not appear to provide any evidence that the conditions in Fishman et al would cause substantial destructurization or dextrinization. To the contrary, Fishman et al teach that the "gelatinized starch solution is prepared by mixing starch with water and heating it above the boiling point of water under pressure for a sufficient time to break down starch granules." (Emphasis added.) See col. 5, lines 1-4. Additionally, Fishman et al employs a starch solution which indicates use of a large amount of water and heating and pressure conditions which provide exudation of the starch molecules from the granules resulting in substantial destructuring for formation of a solution.

Applicant notes with appreciation the withdrawal of the rejection with regard to claim 61. However, claim 34, like 61 recites a density of 800 g/liter to 1500 g/liter (0.8 to 1.5 g/ml) whereas according to Newton et al at col. 5 lines 7-9, a higher density of above about 2 g/ml (2000 g/liter) is critical to Newton et al for achieving an increased residence

time in the stomach. It would be contrary to the disclosure of Newton et al to modify the composition to obtain applicant's claimed density.

Reconsideration and withdrawal of the rejection is respectfully requested.

Claims 25, 26, 28, 30, 31, 35, 37, 38-40, 46, 50, 52, 53, 55, 56, 58, 59, 62, 64-67, 69, 73, 75, 79, 81, 83, 91-93, 95-97, 101, 103, 105, 108, 109, 111, and 112 are rejected under 35 U.S.C. 103(a) as being unpatentable over Desaga (DE 19503993) in view of Loomis et al (US 5,852,114). This rejection is respectfully traversed for reasons as presented in the March 28, 2012 response and below.

Neither Desaga et al nor Loomis et al, taken alone or in combination teach or suggest the use of a plasticized mass comprising starch which is neither substantially destructured nor substantially dextrinized, as claimed in independent claims 25, 27, 52, 54, and 83, and their dependent claims. Even if the references were properly combinable, applicant's claimed products would not be obtained or rendered obvious.

The Examiner submits that Loomis et al discloses that the starch that may be used in the compositions include native or modified starch, gelatinized starch and destructure starch. It is maintained that this indicates that when native, modified or gelatinized starch is used that the starch would not be "substantially destructured" or "substantially dextrinized" because the reference distinguishes destructure starch from the native, modified and gelatinized starches. Therefore, it is asserted, Desaga et al in view of Loomis et al suggest the use of a plasticized mass comprising starch which is not substantially destructured or dextrinized.

However, if starch or gelatinized starch was employed, it would be as an ingredient which is subjected to the intense extrusion conditions which would destructure the starch. As disclosed by Loomis et al:

In compositions prepared from a first polymer, a second polymer and a polysaccharide component, such as a starch component, the starch component may be processed--e.g., gelatinized or destructured--independently from the first polymer and the second polymer, and then included in, or added to, the composition either before or after processing the components used to form the composition. Alternatively, the starch component may be included in the composition while processing the first polymer and the second polymer into the uniform, substantially homogeneous uniform blend. See col. 11 lines 16-25.

In accordance with the present invention, the compositions may be prepared by subjecting the components used to form the inventive compositions to conditions of intensive mixing, with elevated temperature, such as the conditions that are achieved within the screw and barrel of an extruder. The first polymer and the second polymer, and optionally a polysaccharide component, such as a starch component, may be introduced to intensive mixing conditions in the form of granules, pellets or powders, or in a plasticizer as slurries or solutions thereof. (Emphases added.) See col. 11 lines 38-49.

Processing under the intensive mixing conditions described herein should be continued at a temperature that is greater than the melting point of the first polymer, which itself is typically lower than the melting point of the second polymer, and for a time sufficient to cause the first polymer and the second polymer (and other optional components) to become intimately associated by way of blending to form a uniform, substantially homogeneous blend, and under appropriate conditions a melt-blend. (Emphasis Added). See col. 12 lines 22-30.

As discussed above, Loomis et al employs extrusion temperatures of 170 to 205°C in the blending zone and within the range of 210 to 225°C in the last zone and die, and also a very high a L/D of 38, and the removal of any water in the first zone of the extruder, all of which would result in destructuring of starch. See col. 14 lines 18-54.

The Examiner maintains that the claims recite "not substantially destructured or dextrinized", which indicates that the starch may be one or the other (either "not substantially destructured" or "not substantially dextrinized") or both. According to the Examiner, therefore even if the starch is substantially destructured as applicant argues, the

granules are "not substantially dextrinized", meeting the limitation of "not substantially destructured or dextrinized". The claims have been amended to more clearly indicate that the starch is neither substantially destructured nor substantially dextrinized. As discussed above, the starch of Loomis et al is clearly substantially destructured, with the starch molecules being exuded from the granules for polymerization. The Examiner asserts that the instant specification discloses that the plasticized composition forms a melt, which indicates that the starch granules of the instant claims undergo some type of disruption, and Loomis et al disclose the compositions form melts. However, as discussed above, crystallinity of the molecules in the starch granules can be changed to amorphous regions within the starch granules, without having the molecules of starch exude from the granule. To the contrary, in the process of Loomis et al, the starch molecules are exuded from the granules and the granules are destroyed, which is a substantial destructuring. The Examiner asserts that applicant does not appear to provide any evidence that the conditions in Loomis et al would cause substantial destructurization or dextrinization.

As discussed above, Loomis et al discloses the use of extrusion temperatures of 170 to 205°C in the blending zone and within the range of 210 to 225°C in the last zone and the extruder die. See col. 14 lines 30-54. Loomis desires destructured starch and employs extrusion conditions to destructure starch. According to Loomis et al, "when starch is heated under shear in the presence of relatively small amounts of water, the resulting new starch-water composition, in the form of a melt, surprisingly has thermoplastic properties. Those thermoplastic starch compositions have become known as "destructurized starch." See col. 2 lines 16-26. Loomis et al produces polymer blend compositions that are thermoplastic. See col. 1 lines 16-20. Loomis et al may include destructurized starch in the compositions to impart further desirable physical properties and characteristics. See col. 4 lines 59-67. If starch or gelatinized starch was employed, as discussed above, it would be subjected to the intense extrusion conditions which would destructure the starch.



Loomis et al does not teach or suggest avoiding destructuring or dextrinization, or the use of low shear or high amounts of plasticizer, or extrusion residence time, screw speeds, and screw configurations to achieve plasticization without substantial destructurization or dextrinization of the starch. To the contrary, Loomis et al employs high extrusion temperatures, a high L/D, intensive mixing conditions, and low moisture contents to obtain destructured starch and a thermoplastic composition.

Furthermore, as evidence that the Loomis et al extrusion would result in destructuring of the starch component, as discussed above and in the March 28, 2012 Amendment, Bastioli et al discloses that from a microphotograph relating to their comparative experiment 1, it is apparent that the extrusion temperature of 100° C. is too low and does not allow the destructuring of the starch because the microphotograph shows the presence of a large number of still intact starch granules. The analysis, it is disclosed, of the product obtained from example 2 (extrusion temperature 120°C.) shows that the number of intact starch granules has been substantially reduced, although some are still present. On the other hand, it is disclosed, a complete destructuring of the starch is obtained according to example 3 with an extrusion temperature of 140°C. The microphotographs obtained from the material of example 3 does not show intact starch granules according to Bastioli et al. See Bastioli et al U.S. Patent No. 5,462,982 at col. 1 lines 24-36, col. 2 lines 20-41, and col. 4 lines 7-27. The Loomis et al method employs much more intense extrusion conditions than those of Bastioli et al which would clearly destroy intact starch granules resulting in substantial destructuring by the extrusion temperatures of 170 to 205°C in the blending zone and within the range of 210 to 225°C in the last zone and die, and also with the use of a very high L/D of 38, and the removal of any water in the first zone of the extruder, all of which would result in substantial destructuring of starch.

In regard to claims 111 and 112, the Examiner asserts that the starches used by Loomis et al include native and modified starches, which would meet the limitation of the starch being not cooked or a portion of it being not cooked. However, the native starch or

modified starch of Loomis et al employed as an ingredient would still be substantially destructured because it would be subjected to the intense extrusion conditions of Loomis et al, as described above.

Even if the references were properly combinable, employment of the plasticized starch of Loomis et al in the process and composition of Desaga would result in substantial destructure of the starch because it would be subjected to the intense extrusion conditions of Loomis et al.

Reconsideration and withdrawal of the rejection is respectfully requested.

**Obvious-Type Double Patenting (Reinstated Rejection)**

Claims 25 and 52 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 15 of U.S. Patent No. 7,201,923 (previously U.S. Application No. 09/233,443, claim 21). The rejection has been reinstated. The rejection is also applied to claims 30, 31, 37-40, 42, 46, 55, 56, 58, 59, 64, 69, 70, 73, 75, 81-85, 91, 92, 95, 101, 103, 105 and 108-110. This rejection is respectfully traversed.

The Examiner indicates that Applicant has filed a Terminal Disclaimer on June 18, 2003, the Terminal Disclaimer was disapproved on April 12, 2012 and therefore the rejection has been reinstated. In regard to the additionally added claims, it is asserted that the instant claims comprise the same components as the patented claims (patented claims 1-22), the claims differ insofar as the instant claims are genus claims insofar as the instant claims do not disclose a specific source of starch in the independent claims, and the starch is further defined in the instant dependent claims, and therefore the instant claims are obvious over the patented claims. The present claims recite a discrete, solid particles having a substantially uniform shape. However, if the Examiner insists, to avoid any question of double-patenting, applicant will submit a terminal disclaimer upon an indication of allowable subject matter.

Reconsideration and withdrawal of the rejection is respectfully requested.

## **CONCLUSION**

In light of the foregoing amendments and remarks, this application is in condition for allowance, and early passage of this case to issue is respectfully requested. If there are any questions regarding this Amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application.

A request for a one month extension of time and the appropriate government fee are being submitted concurrently herewith.

It is not believed that any additional fees are due. However, the U.S. Patent and Trademark Office is hereby authorized to charge any fees which may be deemed necessary or to credit any overpayments to Deposit Account No. 19-0089 (P32853).

Respectfully submitted,  
Bernhard H. van Lengerich

/Barry I. Hollander/

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Barry I. Hollander  
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November 30, 2012  
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